

Attorney Docket No.: 267/033 (UMD-0055)  
Inventors: Rameshwar, Pranela  
Serial No.: 10/039,272  
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**REMARKS**

Claims 1-77 are pending in this application. Claims 3, 34, 50, 63, and 77 have been amended to correct typographical errors. Claim 37 has been amended to change dependency. Claims 6, 10, 20, 28, 30, 32, 36, 38, 39, 41, 44-46, 48, 49, 51, 53, 54, 56, 58, 60, 66, 67, 69, 71, and 73 have been canceled. No new matter has been added. Applicant is respectfully requesting reconsideration of the restriction requirement in view of these amendments and the following remarks.

The claims of the present application have been subjected to a Restriction Requirement under 35 U.S.C. §121 by the Examiner in this case. The Examiner suggests that restriction of the present invention into the following groups is required:

Group I, claims 1-10 and 21-22, drawn to an isolated polynucleotide comprising SEQ ID NO:1, a vector, host cell and pharmaceutical composition;

Group II, claims 11-12, 14 and 24-25, drawn to an isolated polypeptide of SEQ ID NO:2 and a pharmaceutical composition containing the polypeptide;

Group III, claims 13 and 26, drawn to an isolated antibody immunospecific for the polypeptide of SEQ ID NO:2 and a pharmaceutical composition containing the antibody;

Group IV, claims 15-21 and 23, drawn to a polynucleotide sequence comprising an antisense sequence to a nucleotide of SEQ ID NO:1 and a pharmaceutical composition containing the antisense;

Group V, claims 27-28, drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation

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or proliferation by administering a pharmaceutical composition comprising a HGFIN polynucleotide;

Group VI, claims 29-30, drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation or proliferation by administering a pharmaceutical composition comprising a HGFIN polypeptide;

Group VII, claims 31-32, drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation or proliferation by administering a composition comprising a polynucleotide coding for the antisense sequence to SEQ ID NO:2;

Group VIII, claim 33, drawn to a method of treating a disease associated with abnormal bone marrow cell differentiation or proliferation by administering a pharmaceutical composition comprising an antibody immunospecific for the HGFIN polypeptide;

Group IX, claims 34-36, drawn to a vector for the delivery of an HGFIN therapeutic to a cell for the treatment of leukemia or lymphoma;

Group X, claims 37-49, drawn to a method for introducing an HGFIN therapeutic into a cell, comprising transfecting the cell with a vector or plasmid comprising an expression cassette encoding the HGFIN therapeutic;

Group XI, claims 50-56 and 61, drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a compound of the general formula  $\alpha$ -HGFIN-C and a pharmaceutically acceptable carrier, wherein C is a radioactive moiety;

Group XII, claims 50-54, 57-58 and 61, drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a

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compound of the general formula  $\alpha$ -HGFIN-C and a pharmaceutically acceptable carrier, wherein C is a chemotoxic moiety;

Group XIII, claims 50-54 and 59-61, drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a compound of the general formula  $\alpha$ -HGFIN-C and a pharmaceutically acceptable carrier, wherein C is a toxin protein moiety;

Group XIV, claim 63, drawn to a method of treating a lymphoproliferative disease, comprising administering a biologically effective amount of a composition comprising a compound of the general formula  $\alpha$ -C and a pharmaceutically acceptable carrier;

Group XV, claims 64-69 and 74-76, drawn to a compound for the treatment of a lymphoproliferative disease of the general formula  $\alpha$ -HGFIN-C, wherein C is a radioactive moiety;

Group XVI, claims 64-67, 70-71 and 74-76, drawn to a compound for the treatment of a lymphoproliferative disease of the general formula  $\alpha$ -HGFIN-C, wherein C is a chemotoxic moiety;

Group XVII, claims 64-67 and 72-76, drawn to a compound for the treatment of a lymphoproliferative disease of the general formula  $\alpha$ -HGFIN-C, wherein C is a toxin protein moiety; and

Group XVIII, claim 77, drawn to a compound for the treatment of a lymphoproliferative disease of the general formula  $\alpha$ -C.

The Examiner suggests that the inventions listed as Groups I-XVIII are independent and distinct from each other. It is suggested that each of the invention groups I-IV, IX and XVI-XVIII represent separate and distinct products which are made by materially different methods and are used in materially different methods which have different modes of operation, functions and

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effects. It is further suggested that Groups V-VIII and X-XIV are materially distinct methods because they each have different objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Groups I-IV, IX and the method of Group X are acknowledged as being related as product and process of use; however, the method of introducing HGFIN therapeutic into a cell can be practiced with a materially different material such as a polynucleotide or a polypeptide or an antisense or an antibody or a vector. Groups XVI-XVIII and the method of Group XIII are also acknowledged as being related as product and process of use; however, the method of treating a lymphoproliferative disease can be practiced with a materially different material such as any one of the formulas disclosed in Groups XVI-XVIII. Applicant is required to elect one of the Groups to be examined.

Further, the Examiner suggests that Groups I and X (claims 10, 41 and 48), Groups V-VII and XI-XIII (claims 28, 30, 32, and 51), Group X (claim 44), Groups XII and XVI (claims 58 and 71), and Groups XIII and XVIII (claims 60 and 73) are generic to a plurality of disclosed patentably distinct species and under 35 U.S.C. 121 Applicant is required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Moreover, upon election of one of Group IX (claim 35), Group X (claim 43), Groups XI-XIII (claim 61), or Groups XV-XVII (claim 74), the Examiner has indicated that one HGFIN sequence must be selected as each HGFIN sequence (*i.e.*, sense (DNA, cDNA or RNA) or antisense) is a distinct invention and not a species.

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Applicant respectfully disagrees and traverses this restriction requirement.

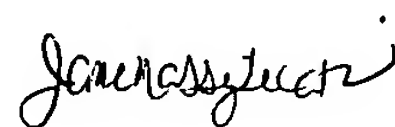
MPEP §803 is quite clear; for a proper restriction requirement, it must be shown (1) that the inventions are independent or distinct AND (2) that there would be a serious burden on the Examiner if the restriction is not required. MPEP 802.01 defines "distinct" to mean that the "two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made there, etc., but are capable of separate manufacture, use, or sale, as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER."

Claims set forth in the instant application relate to HGFIN molecules and methods for using the same. Therefore, a search of the relevant prior art would reveal art related to HGFIN nucleic acids and proteins and methods for using the same. Therefore, no additional burden would be incurred by the inclusion of all eighteen groups of claims in this application. However, should the Examiner maintain the restriction, Applicant respectfully requests reconsideration of the restriction of claims 1-10 and 15-23 into Groups I and IV for the following reasons. Polynucleotides comprising HGFIN sense and antisense nucleic acid sequences would be readily identified as the relevant prior art sequences pertaining to Groups I and IV would be revealed in a search of the nucleic acid sequence of SEQ ID NO:1. Thus, Applicant respectfully requests that claims 1-10 and 15-23 be searched and examined together. Reconsideration and withdrawal of the restriction requirement is therefore respectfully requested.

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However, in an earnest effort to be completely responsive, Applicant hereby elects to prosecute Group I, claims 1-10 and 21-22, drawn to an isolated polynucleotide comprising SEQ ID NO:1, a vector, host cell and pharmaceutical composition, classified in class 536, subclass 23.5, and class 435, subclasses 325, 320.1 and 69.1, with traverse. Further, it should be noted that a species election was not made as Applicant has canceled claims drawn to multiple species in order to facilitate and simplify the search and prosecution of this application.

Respectfully submitted,



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